CHAPTER 3

RISK EVALUATION AFTER THE FEASIBILITY STUDY

After the FS is completed, a remedy is proposed, and, if selected, is documented in the ROD. Following this, the remedy is designed and implemented, and then deletion/five-year reviews of the site take place. This chapter discusses the role of risk information during these activities. Note, however, that not all of these risk evaluations nor a significant level of quantitation may be needed for every site. The guiding principle is that risk evaluations after the FS should be conducted as necessary to ensure that the remedy is protective.

3.1 RISK EVALUATION FOR THE PROPOSED PLAN

The purpose of a risk evaluation during the proposed plan stage is to refine previous analyses conducted during the FS, as needed. If new information becomes available during the public comment period for the proposed plan, additional analysis of the alternatives may need to be conducted at this time. If additional analysis is conducted, it should be conducted for all the alternatives, as appropriate, and not just for the preferred alternative.

3.2 DOCUMENTATION OF RISKS IN THE ROD

Several risk-related analyses should be documented in the ROD. The comparative analysis section should include a discussion of risk as it pertains to the three risk-related criteria: long-term effectiveness, short-term effectiveness, and overall protection of human health and the environment. The discussion of overall protection of human health and the environment should include a discussion of how the remedy will eliminate, reduce, or control the risks identified in the baseline risk assessment and whether exposure will be reduced to acceptable levels. The discussion of long-term effectiveness (and permanence) should address, where appropriate, the residual risk from untreated waste remaining at the site. The part of the decision summary that focuses on the selected remedy should present:

- the chemical-specific remediation levels to be attained at the conclusion of the response action;
- the corresponding chemical-specific risk levels;
- the points (or areas) of compliance for the media being addressed; and
- the lead agency's basis for the remediation levels (e.g., risk calculation, ARARs).

In addition, the ROD should indicate whether the site will require five-year reviews (see Section 3.4). In some cases, additional risk information (e.g., anticipated post-remedy cumulative risk for an environmental medium or for a site) may need to be included in the ROD.

Interim Final Guidance on Preparing Superfund Decision Documents (EPA 1989f), *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions* (EPA 1991d), and RAGS/HHEM Part B provide additional information on documenting risks in the ROD.

3.3 RISK EVALUATION DURING REMEDIAL DESIGN/ REMEDIAL ACTION

The activities during remedy design and implementation that may involve consideration of risk include refining risk evaluations during remedial design, monitoring short-term risks, evaluating attainment of remedial levels in the ROD, and evaluating residual risk.

3.3.1 RISK EVALUATION DURING REMEDIAL DESIGN

The process of evaluating long-term and short-term risks, which began during the FS and may have continued during development of the proposed plan, also may continue during design of the selected remedy for some sites. The purpose for risk evaluations during the remedial design is to ensure that the selected remedy will be protective. These evaluations can be conducted by: (1) refining previous analyses, as needed, and/or (2) identifying the need for engineering controls or other measures to mitigate risks. Methods for evaluating long-term and short-term risks are discussed in more detail in Chapter 2.

3.3.2 MONITORING SHORT-TERM HEALTH RISKS DURING IMPLEMENTATION

If the potential for short-term health effects due to releases during remedy implementation needs to be assessed (e.g., due to high uncertainty concerning predicted risks to communities or remediation workers), a sampling and analysis strategy to accurately determine exposure concentrations should be developed. This strategy may need to consider the following elements:

- location of sampling;
- sample collection and handling procedures;
- chemicals to be monitored and methods used; and
- statistical considerations regarding the analysis of results.

The monitored exposure concentrations should be compared to short-term health-based benchmarks (see Appendix C) to help in determining whether the release presents a threat to human health.

3.3.3 ASSESSING ATTAINMENT OF SELECTED REMEDIATION LEVELS DURING IMPLEMENTATION

The RPM, risk assessor, and others should be involved in developing a sampling and analysis plan to measure whether the selected remedy has attained the remediation levels in the ROD. As in the baseline risk assessment, this sampling and analysis should provide data that can be used to develop RME estimates. This plan is site-specific and may need to consider the same elements presented in Section 3.3.2, plus the relevant remediation levels for the chemicals of concern.

The plan for measuring attainment should ensure that sufficient data to evaluate protectiveness of human health will be available. For example, at a minimum, those chemicals that contribute to major portions of the site risk should be selected for measuring attainment. The two-volume set *Statistical Methods for Evaluating the Attainment of Cleanup Standards* (EPA 1988d) outlines a number of statistical methods that can be used to measure attainment. EPA is developing additional guidance on this topic.

3.3.4 EVALUATION OF RESIDUAL RISK

This step — which may be conducted at completion of the remedy and perhaps during a five-year review (see next section) — may be needed to ensure that the remedy is protective. This step may be different from the assessment of attainment of remediation levels selected in the ROD because it may more closely consider the expected land use and cumulative effects (e.g., due to multiple chemicals or exposure pathways). Residual risk estimates can be conducted at any time after the remedy has commenced until the end of the remedy. Typically, a final evaluation of the cumulative site risk may be done following completion of the final operable unit to ensure that residual risks from multiple contaminants, pathways, and operable units that affect the same individuals are at protective levels.

In general, the same equations, exposure parameters, and toxicity values that were used to determine the baseline risk for a site can be used to assess the final clean-up (risk) level that a remedy has achieved. The concentrations that are used to calculate these risks, however, are the final measured concentrations of the contaminants that remain at the site, not the remediation levels in the ROD. The following are other potential differences between the baseline risk assessment and evaluation of residual risks.

- Significant levels of "new" chemicals (e.g., that were not identified during the baseline risk assessment but that may have resulted from the remedy or were not discovered until after remedy implementation) should be considered in evaluating residual risk.

- Changes in land use since the time of the baseline risk assessment may require changes in exposure parameters (e.g., contact rates, exposure frequency and duration).

- Toxicity values may have been updated since the baseline risk assessment. The most recent toxicity values in IRIS and HEAST should be used in calculating residual risk.

For some sites where engineering or institutional controls rather than treatment-based remedies are employed, the concentrations of chemicals in a contaminated medium may remain the same as the baseline concentrations. The risk will have been reduced or eliminated, however, by mitigation or elimination of the exposure pathway (e.g., by mitigating direct contact with soil by using a cap or institutional controls, or eliminating ingestion of contaminated drinking water by providing an alternate water supply). These risk reductions and associated exposure assumptions should be clearly presented.

3.4 RISK EVALUATION DURING FIVE-YEAR REVIEWS

Section 121(c) of CERCLA provides for reviews of remedies that result in hazardous substances remaining at the site no less often than every five years after the initiation of the remedies. The purpose of the reviews is to assure that human health and the environment are being protected by the remedial alternative that was implemented.

The remainder of this section briefly describes the purpose of five-year reviews, the sites for which five-year reviews are conducted, and the risk-related activities that may be conducted during five-year reviews. More detailed guidance regarding five-year reviews is available in *Structure and Components of Five-year Reviews* (EPA 1991e).

3.4.1 PURPOSE OF FIVE-YEAR REVIEWS

A five-year review is intended to ensure that a remedy remains protective of human health and the environment. The more specific goals of a five-year review are:

- to confirm that the remedy (including any engineering or institutional controls) remains operational and functional; and

- to evaluate whether clean-up standards (based on risk or ARARs) are still protective.

The first goal may be accomplished primarily through a review of the operation and maintenance records for a site and through a site visit and limited analysis. The second goal includes an analysis of requirements that have been promulgated by the federal or state governments since ROD signature to determine whether they are ARARs and whether they call into question the protectiveness of a remedy.

In addition to considering ARARs for substances designated as contaminants of concern in the ROD, the reviews may include changes in ARARs for substances not addressed under contaminants of concern. Where remediation levels in the ROD were based on risk calculations (rather than ARARs), then new information — such as revised toxicity values or exposure parameters — that could influence the protectiveness of the remedy should be considered. Based on this analysis, the reviewer can determine whether the original remediation levels set out in the ROD are still protective.

3.4.2 SITES THAT RECEIVE FIVE-YEAR REVIEWS

Two types of five-year reviews are conducted: statutory and policy. Statutory reviews are conducted for remedies selected after the enactment of SARA where, after the remedy is complete, hazardous substances are present above levels that allow for unlimited use and unrestricted exposure. These sites generally include: (1) sites with remedies requiring access or land-use restrictions or controls (i.e., remedies that achieve protectiveness through the use of engineering or institutional controls); and (2) sites with remedies that achieve protectiveness for the current use, but include restrictions on activities due to limits on exposure (i.e., sites cleaned up to levels that would be protective for a nonresidential land use, but would not be protective for residential or other land use). Policy reviews are conducted for: (1) sites with long-term remedial actions (LTRAs) or other remedies that require five years or longer to achieve levels that would allow for unlimited use and unrestricted exposure and (2) remedies selected before the enactment of SARA where hazardous substances are present above levels that allow for unlimited use and unrestricted exposure.

Statutory reviews may be discontinued only if levels of hazardous substances fall permanently to a point that would allow unlimited use and unrestricted exposure. Policy reviews for LTRAs should be discontinued when the remediation goals specified in the ROD are achieved, assuming these levels allow for unlimited use and unrestricted exposure. Achievement of these levels must be verified by an appropriate period of monitoring.

3.4.3 RISK-RELATED ACTIVITIES DURING FIVE-YEAR REVIEWS

Three levels of effort have been defined for five-year reviews. The following are risk-related activities conducted for the three levels.

- At Level I, the reviewer will consider the risk assessment information contained in the ROD and ROD summary.

- At Level II, the reviewer will conduct a recalculation of the original baseline risk assessment using information obtained during the review (e.g., new toxicity data). If appropriate, additional data may be collected. Ongoing monitoring may provide such data.

- At Level III, the reviewer will reevaluate the risk assessment, and, if appropriate, conduct a new risk assessment. Such an assessment may be appropriate in order to address a new site condition, such as a new exposure pathway. New data may be collected as necessary for the risk assessment. If possible, however, existing data should be used.

The appropriate level of review depends on site-specific conditions and the confidence level for the selected remedy. The proposed level of the first review is to be included in the ROD. A Level I review should be appropriate in all but a few cases where site-specific circumstances suggest another level either at the outset of the review or because findings of the review suggest the need for further analysis. A Level III review would not be proposed in the ROD, but would be initiated in response to specific concerns regarding the performance of the remedy or the risks at the site. The level of effort, particularly for subsequent reviews, also depends on the initial findings of the review. *Structure and Components of Five-year Reviews* (EPA 1991e) provides additional information concerning the appropriate level for reviews and the activities that are conducted at each level.